DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 2, 2015

Symmetry Surgical, Inc.
Mr. Christopher Smith, RAC
Senior Director of QA/RA
3034 Owen Drive
Antioch, TN 37013

Re: K141826
Trade/Device Name: FlashPak® Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: February 18, 2015
Received: February 23, 2015

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141826

Device Name
FlashPak® Sterilization Container System

Indications for Use *(Describe)*
FlashPak® is a reusable rigid container system to be used during immediate use steam sterilization (IUSS or flash) by hospitals and healthcare facilities. It is intended to enable sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement steam sterilization using a 10 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle at 132° C for nonporous items like routine metal instruments. The container is also compatible with pre-vacuum steam sterilization using a 4 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle for nonporous items like routine metal instruments. FlashPak® is recommended for sterilization of lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).

FlashPak® Model/Maximum Instrument Load Weight Recommendation:

9020 w/ 9020-08 Basket - Gravity 3 pounds (1.36 Kg) - Pre-Vacuum 3 pounds (1.36 Kg)

9030 w/ 9030-08 Basket - Gravity 10 pounds (4.55 Kg) - Pre-Vacuum 10 pounds (4.55 Kg)

9040 w/ 9040-08 Basket - Gravity 14 pounds (6.35 Kg) - Pre-Vacuum 14 pounds (6.35 Kg)

9050 w/ 9050-08 Basket - Gravity 16 pounds (7.27 Kg) - Pre-Vacuum 16 pounds (7.27 Kg)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

General Company Information

Company Name:	Symmetry Surgical
Company Address:	3034 Owen Drive Antioch, TN 37013
Company Telephone:	615-964-5392
Contact:	Christopher M. Smith Sr. Director of QA/RA
Contact Address & Telephone:	3034 Owen Drive Antioch, TN 37013 615-964-5392
Date:	April 2, 2015
Device Trade Name:	FlashPak® Sterilization Container System
Common Name:	Wrap, Sterilization
Classification, Regulation # and Product Code:	Class II - 880.6850 - FRG
Predicate Device:	FlashPak® Sterilization Container System, K113776

Device Description:

The FlashPak Container System consists of a Radel® lid and base that together fully enclose a removable metal wire basket that holds items to be sterilized. A silicone gasket creates an air tight seal between the lid and base by means of metal latches. Two pressure actuated valves; one in the center of the lid and one in the center of the base, allow ingress and egress of steam sterilant into the container during the sterilization cycle and when closed form an airtight enclosure against separate silicone seals. The container comes in four sizes and is indicated for use with gravity-displacement and dynamic-air-removal sterilization modes recommended in ANSI/AAMI ST79 for immediate use steam sterilization (IUSS). Approved chemical indicators are recommended for use during each sterilization cycle.

Intended Use:

The intended use of the predicate device was changed to add additional steam sterilization indications. The 3 minute gravity displacement cycle at 132 ºC and 3 minute dynamic-air removal cycle at 132 ºC were validated and added to the following intended use statement.

'FlashPak® is a reusable rigid container system to be used during immediate use steam sterilization (IUSS or flash) by hospitals and healthcare facilities. It is intended to enable sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement steam sterilization using a 10 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle at 132° C for nonporous items like routine metal instruments. The container is also compatible with pre-vacuum steam sterilization using a 4 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle for nonporous items like routine metal instruments. FlashPak is recommended for sterilization of lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).

FlashPak® Model/Maximum Instrument Load Weight Recommendation:

9020 w/9020-08 Basket – Gravity 3 pounds (1.36 Kg) – Pre-Vacuum 3 pounds (1.36 Kg)

9030 w/9030-08 Basket – Gravity 10 pounds (4.55 Kg) – Pre-Vacuum 10 pounds (4.55Kg)

9040 w/9040-08 Basket – Gravity 14 pounds (6.35 Kg) – Pre-Vacuum 14 pounds (6.35 Kg)

9050 w/9050-08 Basket – Gravity 16 pounds (7.27 Kg) – Pre-Vacuum 16 pounds (7.27 Kg)'

Substantial Equivalence Discussion

The predicate device is the FlashPak Sterilization Container System cleared under 510(k) #K113776. The predicate device and the subject device are physically identical. They are the same device. The differences between the predicate and the subject device involve the steam sterilization parameters recommended in the instructions for use (IFU) and intended use statement. The subject device has additional immediate use steam sterilization parameters recommended for its use that were taken from ANSI/AAMI ST79 and were validated for efficacy.

A comparison of the similarities and differences between the predicate device and the subject device is provided in the table below. The table follows the elements of interest defined in the guidance document; Draft Guidance for Industry and FDA—Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities of March 7, 2002.

ELEMENT	PREDICATE	SUBJECT DEVICE
Intended Use	FlashPak® is a reusable rigid container system to be used during flash sterilization by hospitals and healthcare facilities. It is intended to enable flash sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement flash sterilization using a 10 minute cycle at 132° C and with pre-vacuum flash sterilization using a 4 minute cycle at 132° C. FlashPak is recommended for surface sterilization of stainless steel instruments and for lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).	FlashPak® is a reusable rigid container system to be used during immediate use steam sterilization (IUSS or flash) by hospitals and healthcare facilities. It is intended to enable sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement steam sterilization using a 10 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle at 132° C for nonporous items like routine metal instruments. The container is also compatible with pre-vacuum steam sterilization using a 4 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle for nonporous items like routine metal instruments. FlashPak is recommended for sterilization of lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).
	Container: Radel R5000 series base and lid; SS (304) Instrument Basket;	

ELEMENT	PREDICATE	SUBJECT DEVICE
Material Composition	SS (304) Latches; Clear Medical Grade Silicone Gasket and Valve Seal; SS (300) Hardware; Sintered SS Filter Disk; Silicone Lid Vent Button Valve: SS (304) Bellows; SS (316) Bracket	Same as predicate
Physical Properties	Materials used in the FlashPak are commonly used in many other legally marketed sterilization trays and cases. Physical properties of the system materials and construction have a demonstrated long history of safe and effective use for this application.	Same as predicate
Chemical Properties	Materials used in the FlashPak are commonly used in many other legally marketed sterilization trays and cases. Chemical properties of the system materials and construction have a demonstrated long history of safe and effective use for this application.	Same as predicate
Configurations/Dimensions	Container Sizes: (11" x 11" x 7") #9020 (20" x 11" x 8"), #9030 (24" x 11" x 9") #9040 (24" x 13" x 9") #9050	Same as predicate

ELEMENT	PREDICATE	SUBJECT DEVICE
Air Permeance	N/A Container operates with valves, no filters, wraps or perforations	N/A
Percent of Surface Perforations	N/A Container is not perforated	N/A
PERFORMANCE	**PREDICATE**	**NEW DEVICE**
Sterilant Penetration	<u>Sterilization Efficacy</u> Gravity-displacement Cycle: • 10 minutes at 132°C(270°F) for porous and cannulated devices Dynamic-air-removal Cycle • 4 minutes at 132°C(270°F) for porous and cannulated devices <u>Sterilant Penetration</u> Three thermal mapping studies for each of the two sterilization modes demonstrating a precise match (within seconds) between the chamber and container temperature profiles.	Same as predicate with the added indications for: Gravity-displacement Cycle: • 3 minutes at 132°C(270°F) for nonporous and routine metal devices Dynamic-air-removal Cycle • 3 minutes at 132°C(270°F) for nonporous and routine metal devices
Microbial Barrier Properties (Packaging Integrity)	The container completely encapsulates the items sterilized inside with the use of a silicone lid gasket, a silicone lid vent, sintered SS microfilter and silicone valve seals to provide an effective microbial barrier during transport to the point of use immediately	Same as predicate

ELEMENT	PREDICATE	SUBJECT DEVICE
	after sterilization. • Container passed a microbial aerosol challenge test by preventing microbial ingress during a one hour exposure to aerosolized microbes in a closed chamber.	
Material Compatibility	Materials used in the FlashPak are commonly used in many other legally marketed sterilization trays and cases. The system materials and construction have a demonstrated long history of safe and effective use for this application.	Same as predicate
Toxicological Properties (Biocompatibility, including Sterilant Residue Limits)	Materials used are either medical grade polymers or stainless steel. Instruments placed in the container only come in contact with the Stainless Steel wire basket. Cytotoxicity and Intracutaneous Reactivity studies were completed on the final configuration.	Same as predicate
Shelf Life	N/A FlashPak is intended for immediate use steam sterilization	Same as predicate
Drying Time	N/A FlashPak is intended for immediate use steam sterilization	Same as predicate
Aeration Time & EtO Residuals	N/A FlashPak is only recommended for steam sterilization	N/A

Technological Characteristics:

The technological characteristics of the subject device are identical to the predicate since there have been no physical changes made to the device. The materials, manufacturing and fundamental scientific technology are the same.

Performance Data:

The sterilization parameters tested were taken from ANSI/AAMI ST79 for IUSS. Testing consisted of sterilization efficacy studies for the additional steam sterilization indications. The over kill test method described in ISO 17665-1 was applied. A worst case loading configuration was utilized; i.e. maximum recommended weight of routine metal instruments.

	Maximum Instrument Load Weight Recommendation	
FlashPak Model	**Gravity**	**Pre-Vacuum**
9020 w/ 9020-08 Basket	3 pounds (1.36 Kg)	3 pounds (1.36 Kg)
9030 w/ 9030-08 Basket	10 pounds (4.55 Kg)	10 pounds (4.55 Kg)
9040 w/ 9040-08 Basket	14 pounds (6.35 Kg)	14 pounds (6.35 Kg)
9050 w/ 9050-08 Basket	16 pounds (7.27 Kg)	16 pounds (7.27 Kg)

Biologic indicators (BI) with resistant Geobacillus Stearothermophilus were placed throughout the container among the devices and four devices were directly inoculated. Half cycles were run three times for each sterilization mode, gravity displacement and dynamic-air removal. Following sterilization the BIs were aseptically removed and processed to culture media then incubated to observe for any microbial growth. In every run there was no observed microbial growth indicating an SAL of 10^{-6} was achieved. Positive and negative controls were concurrently processed and passed as well.

Conclusion: Performance testing data demonstrates the the FlashPak® Sterilization Container is substantially equivalent to the predicate device.